Advanced Cardiovascular Systems, Inc.,

Plaintiff,

v.

Medtronic, Inc.,

Defendant,

No. C95-03577-DLJ

ORDER

On August 15, 2008, defendant Medtronic filed a Motion to Modify Injunction. On October 3, 2008 this Court held a hearing on the matter. Plaintiff Advanced Cardiovascular Systems was represented by Edward Mas, David Headrick, Scott McBride and Kevin O'Connor of McAndrews, Held & Malloy and by Robert McCauley of Finnegan, Henderson, Farabow, Garrett & Dunner. Medtronic was represented by Robert Van Nest, Ashok Ramani and Rebekah Punak of Keker & Van Nest and by James Elacqua, Noemi Espinosa, Hieu Phan and Tina Soriano of Dechert, LLP. Having reviewed the papers and having heard oral argument on this matter, the Court finds the following.

I. Introduction

On May 17, 2000 this Court entered an injunction against Medtronic from infringing claim 3 of the Yock patent, U.S Patent No. 5,451,233 ('233) owned at that time by Advanced CardioVascular Systems ("ACS") and now owned by Abbott Laboratories ("Abbott"). The expiration provision of the injunction states that the injunction will stay in effect "until October 29, 2008 or other legal expiration of the patent."

On July 25, 2008, Yock filed a patent extension application for the '233 patent with the Patent and Trademark Office (PTO) pursuant to the Hatch-Waxman Act, as codified in 35 U.S.C § 156. The extension would benefit Abbott, who now owns the patent. This section provides for an additional period of patent protection if the patent holder was precluded from benefitting from the patent during the term of the patent because a medical device using the patent was pending FDA approval.

That application for extension has now been granted by the PTO on an interim basis until October 29, 2009, which has the effect of both extending the term of the patent and the term of the injunction. Medtronic now comes before the Court arguing that the injunction should be dissolved on October 29, 2008 despite the PTO's actions because to fail to do so would be inequitable to Medtronic.

II. Factual Background and Procedural History

ACS and Medtronic are companies engaged in developing, manufacturing, promoting, and selling medical devices, including catheters used in percutaneous transluminal coronary angioplasty (PTCA). These two parties have been involved in multiple complex patent infringement suits involving the treatment of heart disease with catheters. (Abbott Laboratories is now the successor in interest to ACS on the Yock patent.)

A. The Relevant Medical Devices

Coronary artery disease is a disease of the heart in which a deposit of plaque builds up in a coronary artery and restricts blood flow through the artery. The resulting blockage is known as a stenosis.

The PTCA was first introduced in the mid-1980's as a new minimally invasive medical procedure replacing the need for surgery in the treatment of this disease. A catheter is inserted into the femoral artery in the groin area, then threaded through the aorta and into the arterial system. When the stenosis area is reached, a balloon at the tip of the catheter is expanded which compresses the stenosis and opens the artery. This balloon dilation procedure was improved in the mid-90's when a thin metal cylinder, called a stent, was also threaded through to the stenosis area then expanded and left implanted at the treatment site to maintain the opening of the artery. The latest advance, introduced in 2003,is based upon the fact that some drugs will interfere with restenosis, which is a condition where the blockage returns after it has been once treated. This advance, called Drug-Eluting Stents (DES), is accomplished by coating the bare metal stent with a mixture of a polymer and an inhibiting drug which is then released over time into the treatment site in the artery.

From the beginning these treatment devices have required a delivery system which enables the catheter, the balloon and the stent to be threaded to the treatment site and then withdrawn. The first delivery system was called an “over-the-wire” system.

Later a "multi-exchange" system was introduced. The latest system, a "rapid-exchange" (RX) system was introduced in 1991 following its invention by Dr. Paul Yock. That invention was patented as the '233 patent which is the subject of this law suit.

Absent an extension by the PTO, the Yock patent is scheduled to expire on October 29, 2008. On July 25, 2008, Yock timely filed an application for patent extension pursuant to the Hatch-Waxman Act as codified in 35 U.S.C. § 156.

The application for extension was based upon an U.S. Food and Drug Administration (FDA) regulatory review of a PTCA device owned by Abbott called the Xience™ V EECSS (Everolimus Eluting Coronary Stent System). Abbott represented to the PTO that the Yock '233 patent "claims" that medical device. Upon completion of the regulatory review, the PTO approved the device for commercial marketing on July 2, 2008 by awarding it Pre-market Approval (PMA). Abbott requested an extension of 937 days inasmuch as the FDA review process had begun on May 4, 2005. The PTO considered the application and on October 10, 2008 found that the subject patent was eligible for extension of the patent term under 35 USC § 156. The PTO then granted an interim extension fo the patent term for a period of one year from the original expiration date of the patent term, under 35 U.S.C. §156(e)(2), to allow the PTO to make "a final determination of the length of the regulatory review" period. PTO Letter of 10/10/08 attached to the 10/15/08 Statement of Recent Decision. As a result of this ruling there will be no

"legal expiration" of the term of the '233 patent until October 29, 2009.

The Xience PTCA is a medical device with four basic components: (1) a thin metal balloon expandable stent; (2) a drug (Everolimus); (3) a polymer mixed with the drug and then coated on the stent; and (4) a delivery system (the FDA approved use of any of the three available delivery systems).

Medtronic has developed a competing drug-eluting stent system called "Endeavor." The FDA review process for Endeavor overlapped the review time for the Xience. It is now complete and Endeavor was approved for sale as of February 1, 2008. Although the Endeavor system also contains four elements (a stent, a drug, a polymer and a delivery system) the stent, the drug and the polymer in the Endeavor system are different than those components of the Xience system. Medtronic obtains the drug and the polymer for the Endeavor system from Abbott. Endeavor has also been approved for use with any of the three delivery systems. The current injunction bars Medtronic from marketing the Endeavor with the rapid-exchange system, but Medtronic expects that if it is able to market the Endeavor with a rapid-exchange delivery system, its share of the drug-eluting stent market will greatly increase.

B. Procedural History

On October 10, 1995 ACS filed its complaint against Medtronic (C-95-3577) alleging that Medtronic's PTCA catheter, known as the Falcon catheter, willfully infringed the Yock patent. ACS sought injunctive and monetary relief, including

treble damages and attorney's fees. On March 12, 1996, ACS filed an additional suit (C-96-0942) alleging willful infringement by Medtronic of the '346 patent. The two cases were related in this Court.

Prior to trial, ACS determined that it would pursue infringement claims only for infringement of Claim 3 of the '233 patent and the question of whether Medtronic willfully infringed Claim 3 of the '233 patent. A jury trial was held in October and November 1999. The jury awarded plaintiff ACS $3,418,508 in lost profits and $2,032,500 in reasonable royalty rate damages, and found that Medtronic had willfully infringed Claim 3 of the '233 patent.

On November 24, 1999, the parties filed several post-trial motions. ACS moved for enhanced damages and attorney fees and for a permanent injunction prohibiting patent infringement. On December 1, 1999, the parties filed stipulations and proposed orders concerning the amount of ACS's prejudgment and post-judgment interest and the scope of a permanent injunction. On December 10, 1999, Medtronic filed a statement of conditional non-opposition to ACS's motion for entry of a permanent injunction. ACS was directed to prepare a proposed form for judgment in this case and to share the draft with Medtronic. If Medtronic disagreed with the proposed judgment, it was permitted to file a memorandum stating its position for determination by the Court. After briefing, the parties stipulated to the form of the injunction and the Court entered the current permanent injunction.

III. Legal Standard

A. Modification of a Final Judgment

Federal Rule of Civil Procedure 60 governs the Court's ability to offer relief from a judgment or order. Rule 60(b) provides in pertinent part that:

> On motion and just terms, the court may relieve a party or its legal representative from a final judgment, order, or proceeding for the following reasons:
>
> . . .
>
> (5) the judgment has been satisfied, released or discharged; it is based on an earlier judgment that has been reversed or vacated; or applying it prospectively is no longer equitable; or
>
> (6) any other reason that justifies relief.

FRCP Rule 60(b).

A district court's decision granting, denying, or modifying an injunction in a patent case is reviewed for abuse of discretion. Amado v. Microsoft Corp. 517 F.3d 1353 (Fed. Cir. 2008); Lab. Corp. of Am. Holdings v. Chiron Corp., 384 F.3d 1326, 1331 (Fed.Cir.2004)

B. Extensions of Patent Protection under the Hatch Waxman Act

The Hatch-Waxman Act provides for a limited extension of the term of a patent for a drug, or in this case, a medical device, for which marketing and sales were delayed pending the FDA approval process. The patent restoration portion of the Act is codified in 35 U.S.C. § 156 which reads in pertinent part:

(a) The term of a patent which claims a product, a

> method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b), if--
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> (1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension;
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> (2) the term of the patent has never been extended under subsection (e)(1) of this section;
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> (3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of paragraphs (1) through (4) of subsection (d);
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> (4) the product has been subject to a regulatory review period before its commercial marketing or use;
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> (5)(A) except as provided in subparagraph (B) or (C), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred;
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> . . .
>
> (e)(1) a determination that a patent is eligible for extension may be made by the Director solely on the basis of the representations contained in the application for the extension. If the Director determines that a patent is eligible for extension under subsection (a) and that the requirements of paragraphs (1) through (4) of subsection (d) have been complied with, the Director shall issue to the applicant for the extension of the term of the patent a certificate of extension, under seal, for the period prescribed by subsection (c). Such certificate shall be recorded in the official file of the patent and shall be considered as part of the original patent.
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> (2) If the term of a patent for which an application has been submitted under subsection (d)(1) would expire before a certificate of extension is issued or denied under paragraph (1) respecting the application, the Director shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.
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> 35 U.S.C. § 156

IV. Discussion

A. Hatch-Waxman

The overlap of Patent and Food and Drug laws can work a *de facto* distortion of the legal term of a patented invention. When a patented invention is unable to reap a profit for the patent holder because it cannot be used in the market during the time it is subject to a regulatory FDA review, the term of the patent is effectively shortened. On the other hand, because the Federal Circuit has held that conduct solely intended to prepare a product for future entry into the market is, nevertheless, infringing conduct, the term of a patent can be effectively lengthened. In the latter situation, a competitor cannot engage in the conduct necessary to gain FDA approval until after the patent has expired and the resulting passage of preparatory time results in a *de facto* extension of the patent term. The Hatch-Waxman Act of 1984 was designed to respond to both of these distortions by providing for an extension of the patent term when the invention has been kept out of the market by FDA review, and for a shield from infringement suits where the conduct is solely for the purpose of obtaining FDA approval. According to the Supreme Court, "the 1984 [hatch-waxman] Act was designed to respond to two unintended distortions of the . . . patent term produced by the requirement that certain products must receive premarket regulatory approval." El Lilly & Co. v. Medtronic., Inc., 496 U.S. 661, 669 (1990).

The Federal Circuit has stated in AbTox Inc. v. Exitron Corp., 122 F3d. 1019 at 1028-29 (Fed. Cir. 1997):

> The 1984 Act added two fundamental concepts to the patent statute. Section 202 of the 1984 Act added the infringement shield of 35 U.S.C. § 271(e). Of equal importance, section 201 of the 1984 Act supplied a partial restoration of patent terms when the lengthy regulatory approval process delays marketing of patented inventions. Thus, section 201 added the patent term extensions of 35 U.S.C. §§ 155-56 (1994).
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> As recognized by the Court in *Eli Lilly,* the infringement shield of section 271(e) and the patent term extension of section 156 are the result of debate and compromise. Section 156 supplied patentees, mostly large research and development operations, the benefits of term extensions to erase the de facto reduction of their patent term. Section 271(e) supplied potential infringers, for example generic drug manufacturers, the benefits of an infringement shield to erase the de facto extension of the patent term caused by the requirement to await patent expiration before starting the tests for regulatory compliance. Thus the 1984 Act supplied tradeoff benefits to competing segments of the pharmaceutical industry. From the perspective of R & D pharmaceutical corporations, for instance, the law giveth, section 156, and the law taketh away, section 271(e)(1).
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> Id.

The most recent statement from the Federal Circuit is in Provenis Scientific Corp. V. Innova Systems, Inc., No. 2007-1428, 2008 WL 2967100 (Fed. Cir. Aug. 5, 2008), where the court states that Hatch-Waxman was intended to provide patent term extensions for those patentees whose "market entry was delayed pending regulatory review [because] the early years of the patent term were spent getting premarket approval for the patented invention rather than generating profits. Id. at *3.

The PTO is responsible for administering the patent term provisions of Hatch-Waxman and one of its interpretations of that Act is particularly important in this case. The Xience PTCA is a "combination product" with separate components which

can separately require FDA approval. Of the four major components of the Xience PTCA only one, the RX delivery system, is covered by the Yock patent. In such a case, the PTO liberally construes the statutory provision requiring that a patent "claims a product" to mean that a patent claiming any component part of a medical device is eligible for extension. See February 20, 2008 letter of Jefferson D. Taylor, Director of Governmental Affairs of the PTO to Congressman Howard L. Berman. Phan Dec. ¶ 19, Ex. 16. This interpretation is the basis for the PTO decision that review of one component of the four component Xience PTCA renders the '233 patent eligible for extension under section 156.

B. Use of the '233 Yock Patent

The PTCA medical device is now an essential part of modern day treatment for coronary disease. The original balloon dilation catheter has been improved by adding a bare metal stent which in turn has been improved by coating the stent with a polymer/drug mixture. DES systems are now the state-of-the-art PTCAs. The '233 Yock rapid-exchange delivery system is also the state-of-the-art delivery system for PTCAs. The RX has been and is now being used for all types of PTCAs. A recent survey indicated that 80% of treating doctors prefer the RX system for PTCAs.

In addition to its use in the Xience DES product, Abbott and its predecessors have used the RX in several other PTCA devices listed below.

PTCA	Date FDA Issued a PMA

Simpson-Robert Coronary Balloon Dilation Catheter	April 20, 1990
ACS Multi-Link Coronary Stent System	November 5, 1998
PK Mini-rail RX PTCA Catheter	June 11, 2003
Multi-Link RX/OTW Vision Coronary Stent System	July 16, 2003

In the present DES PTCA market there are four major players: Johnson & Johnson (J & J)(successor to Cordis); Boston Scientific (BSC); Abbott; and Medtronic.

BSC and Johnson & Johnson have the largest share of the DES market. Both use the '233 Yock RX pursuant to a license from Abbott. These two companies have been granted PMAs for some nine PTCA product lines using the '233 Yock RX. See Phan Dec. ¶ 26. One of BSC's products, the Promus DES, is identical to Abbott's newly approved Xience, and the products are simply sold under different brand names. Phan Reply Dec., Ex. 9.

C. What Law Applies – Federal Circuit or Ninth Circuit

Although the parties agree that the Court's power to modify the injunction emanates from Federal Rule of Civil Procedure 60(b), they do not agree on whether this Court is bound by the interpretation of that section as applied in the Ninth Circuit or by the Federal Circuit. Medtronic asserts that Ninth Circuit law controls and Abbott contends that Federal Circuit law controls.

Abbott argues that modification of the injunction turns on substantive patent law issues, and that a district court's decision to modify an injunction in a patent case will be

reviewed by the Federal Circuit in the event of an appeal. Abbott would prefer Federal Circuit law to apply, as then the moving party would have to show: "(1) a substantial change in circumstances or law since the injunction was entered, (2) extreme and unexpected hardship in compliance with the injunction's terms, and (3) a good reason why the court should modify the permanent injunction." This test comes from the 1932 Supreme Court test in United States v. Swift & Co., 286 U.S. 106, 119 (1932), which the Federal Circuit still follows in injunction cases. In contrast, all other circuits, including the Ninth Circuit, follow the Supreme Court holding in Rufo v. Inmates of Suffolk County Jail, 502 U.S. 367, 384, 393 (1992)(as adopted by the Ninth Circuit in Bellevue Manor Assocs. v. United States, 165 F.3d 1249, 1254 (9th Cir. 1999)).

As support for the proposition that the Court should follow the Federal Circuit on this issue, Abbott cites to Laboratory Corp. of America Holdings v. Chiron Corp., 384 F.3d 1326 (Fed. Cir. 2004). However, the Lab Corp case is not in apposite. In Lab Corp, the Federal Circuit was called upon to decide between Federal Circuit and Third Circuit law on threshold issues affecting its jurisdiction over an appeal, not on the standard for modifying an injunction. Id at. 1331. ("[w]hile in some matters of procedural or substantive law this circuit has concluded that we will follow the law as interpreted by the circuit in which the district court is located, such deference is inappropriate on issues of our own appellate jurisdiction).

Abbott concedes that if the issue at bar were "purely

procedural", the Federal Circuit would apply Ninth Circuit law. Moreover, Abbott itself cites to Ninth Circuit cases on this issue admitting that "certain principles are applicable regardless of what Circuit's law applies, and the Federal Circuit looks to persuasive authority from other jurisdictions because its authority regarding Rule 60(b) is not well developed." Abbott Motion in Opposition at p.8, n.10. Broyhill Furniture Indus., v. Craftmaster Furniture Corp., 12 F.3d 1080, 1083 n.1. (Fed. Cir. 1993).

In the Ninth Circuit, the standard for modification of injunctive relief is "flexible" and courts are directed to take into account all of the circumstances in determining whether to modify or vacate a prior injunction. Bellevue Manor Assocs. v. United States, 165 F.3d 1249, 1254 (9th Cir. 1999). In Bellevue Manor and in the Supreme Court case of Rufo on which it relied, the parties sought modification of an injunction (in the Bellevue case) and a consent decree (in the Rufo case) due to a "a *bona fide,* significant change in subsequent law".

While Abbott argues that there should be a separate standard for patent cases, the Ninth Circuit rejected the proposition that the standard of review for modification of an injunction should be different based on whether the "case is characterized as an institutional reform case, a commercial dispute, or private or public litigation." Bellevue Manor at 1254. ("Different considerations may have greater or lesser prominence in different cases, not because the cases are characterized one way rather than another but because equity demands a flexible response to the unique conditions of each

case.")

Thus, under Bellevue the moving party must satisfy the initial burden of showing a significant change either in factual conditions or in the law warranting modification of the decree. The district court must then determine whether the proposed modification is suitably tailored to resolve the problems created by the changed factual or legal conditions. Given that a court should not ordinarily modify a decree "where a party relies upon events that actually were anticipated at the time it entered into a decree" the standard of both the Ninth Circuit and the Federal Circuit become very similar. Rufo, 502 U.S. at 385, 112 S.Ct. 748 ("If it is clear that a party anticipated changing conditions that would make performance of the decree more onerous but nevertheless agreed to the decree, that party would have to satisfy a heavy burden . . .under Rule 60(b).")(citation omitted); U.S. v. Asarco Inc. 430 F.3d 972 (9th Cir. 2005).

With this background, the Court will look at the totality of the circumstances to determine an equitable result.

D. Should the Court Modify the Injunction

As noted above, a court should not ordinarily modify a decree "where a party relies upon events that actually were anticipated at the time it entered into a decree. Rufo, 502 U.S. at 385, 112 S.Ct. 748 (citation omitted). See also U.S. v. Asarco Inc., 430 F.3d 972 (9th Cir. 2005).

Abbott first argues that an injunction is like a consent decree and that a consent decree, like a contract, must be discerned within its four corners. Id. at 980. The terms of

the injunction at issue here state that the injunction will last "until October 29, 2008, **or other legal expiration of the [Yock] '233 patent**." (emphasis added).

Looking solely to the language of the injunction itself it is clear that the parties and the Court contemplated that there might be an expiration date other than the October 29, 2008 date on which Medtronic now focuses.

If the Court were to look beyond the language of the injunction to extrinsic evidence, the record indicates that Medtronic was surely aware of this language. In correspondence between counsel for the parties, an original draft of the injunction by ACS counsel read that the injunction should expire on October 29, 2008. Counsel for Medtronic amended the language to read "October 29, 2008 **or other expiration of the [233 patent]**." See Exhibits D,H to the McBride Declaration and also Exhibit I, Medtronic's Proposed Form of Judgment dated 5/3/00 at p.2 (emphasis added). Abbott's counsel overstates the significance of this exchange by saying that Medtronic "insisted" on the language. Medtronic's "insistence" was really a desire to see "uniformity of inconsistent language." Nonetheless, the correspondence clearly demonstrates that Medtronic was aware of this particular language. See also Exh. J., (letter to the Court stating Medtronic's counsel's attempts to ensure that the terms were clear and comported with federal precedent.) Additionally Medtronic had to have been aware of the potential import of that language, having itself argued to the Supreme Court in other cases about the availability of section 156 extensions to medical devices. (See Exh. M.).

Based on the above, Medtronic bears a heavy burden to demonstrate that there is a significant factual or legal change which warrants a modification of the injunction.

Medtronic argues that the most persuasive changed legal circumstance is the Supreme Court decision in eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006) which was decided after this Court had already entered the permanent injunction, but whose principles are to be applied by this Court when looking at a modification of the injunction. EBay represents a radical departure from the legal context which existed at the time this Court originally entered the permanent injunction.

In eBay, MercExchange sought to license its business method patent to eBay, but no agreement was reached. Merc Exchange then sued eBay for patent infringement. The jury found that eBay had infringed the patent, and that damages were appropriate. The District Court denied MercExchange's motion for permanent injunctive relief. The Federal Circuit reversed the District Court holding as a "general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances." Id.

On review, the Supreme Court disagreed. The Supreme Court looked instead to "well-established principles of equity" and held that even in a patent case, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant permanent injunctive relief. After eBay, when seeking injunctive relief, plaintiff bears the burden of demonstrating: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages,

are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

There has also been a change of fact. When the permanent injunction was issued it was recognized that there could be a circumstance where the patent term was extended. At that time, however, that recognition was conceptual only -- whether or not there would be an extension was simply speculation. At this time, however, the factual context for extension is known. The PTO has indicated that the possible trigger for an extension under Sec. 156 is the regulatory review by the FDA of Abbott's medical device known as the Xience. There is also an eight year period of historical factual context. The Court no longer needs to speculate, there is a new factual context.

Given the changes in law and fact, the Court believes that consideration of a modification of the injunction under Rule 60(b) is appropriate and that the eBay decision governs that consideration.

Because the eBay decision stresses that equitable considerations prevail in looking at injunctive relief, and Medtronic's request to make changes to the current permanent injunction is also based on the equitable principles embodied in Rule 60(b), this Court finds that it cannot ignore the factors the Supreme Court has set forth in eBay when weighing the equities of Medtronic's request.

E. The eBay Factors

This Court is not the first court to look at the balance of the eBay factors as it relates to an injunction by Abbott against Medtronic. The same issue has just recently been reviewed and decided by the District Court in Delaware in a suit by ACS which sought a permanent injunction against Medtronic based on its infringement of a patent for the stent Medtronic uses in the Endeavor system. Advanced CardioVascualr Sys., Inc. V. Medtronic vascular, Inc., Civ. No. 98-80 SLR. Sept. 26, 2008, attached to the Statement of Recent Decision dated 9/30/08. In that case, the District Court reviewed the eBay factors and declined to issue a permanent injunction. While the procedural posture of that case is obviously different, the same equitable considerations are at play in this case.

(1) Irreparable Injury

First, the Court notes that the only issue properly before it is the potential modification to end the injunction on October 29, 2008. The Court has no jurisdiction in this case to order the PTO to take any particular action on the extension application.

Second, if the Court were to end the injunction, the only detriment to Abbott would be the loss of a potential contempt claim before this Court. As the PTO has granted an interim extension of the patent protection, Abbott still has that extension of the term of the Yock patent as the basis of any future claim of infringement against Medtronic.

Both Abbott and Medtronic are multi-billion dollar companies which have spent vast sums on litigation over these

patents and medical devices. They are direct competitors in the market for DES PTCAs. There are two other competitors in this market, both of whom have larger market shares greater than either Abbott or Medtronic.

For the past eight years, Abbott has enjoyed the protective benefit not only of the patent but also of the Court's injunction. While ending the injunction might result in some market share loss to Abbott by Medtronic DES sales, Abbott would have a claim for damages if that were the case, and nothing suggests that this loss could have any significant effect on the continued ability of Abbott to effectively compete in the DES market or to continue to invest in relevant research and development.

Other courts have denied injunctions where companies were as large as these and where money damages were available. See Praxair, Inc. v. ATMI., Inc., 479 F. Supp.2d 440, 443-444 (D. Del. 2007). Abbott will not suffer an irreparable injury in this case if the Court modifies the injunction.

(2) Adequacy of Monetary Damages

When the Delaware Court reviewed the issue of adequacy of monetary damages in the Abbott v. Medtronic case being litigated in that Court, it focused on the fact that Abbott had licensed the patented product in contention to significant competitors. The same facts are present in this case. Abbott has licensed the Yock patent for at least eight years to both Boston Scientific and also to Johnson & Johnson. See Phan Decl. at Exs 6, 8. As Abbott is fully aware, those two companies in turn have exploited those licenses in nine

different product lines and achieved market shares in the overall PTCA stent market that exceeds Abbott's. See Phan Decl. ¶ 26

These acts demonstrate that Abbott has been willing to accept payment in lieu of exclusive control over the patent. As a general rule, courts will find that monetary damages are sufficient in such cases. This Court believes that rule applies in this case as well.

(3) Balance of Hardships

(A) Hardship on the Parties

Depending on the decision as to whether or not the present injunction is modified, either Abbott or Medtronic will suffer some level of hardship. If the injunction remains, Medtronic's Endeavor DES using the RX delivery system cannot be sold without acting in contempt of this Court. Each lost sale of the device can be considered a measurable loss, but the greater loss would be the inability to enter and establish a position based on a state-of-the-art product in the important, dynamic DES product market. If the injunction is dissolved, Abbott would lose the power to use the Court's contempt power to prevent market entry by Medtronic. Each Medtronic sale could mean that Abbott has lost the revenue it would have earned had it made the sale through one of its DES products. The potential hardship to Abbott, however, is mitigated by the fact that Abbott has been given a *de facto* patent extension by the PTO and can sue Medtronic for infringement on any such sale. It is difficult to measure these hardships in any objective basis, but when we add the fact that the Court has already

decided that Abbott has an adequate damages remedy for any such sale, it would appear that the balance, for this injunction factor, tips in favor of Medtronic. It should be noted, however, that in the Court's mind, considering the balance of competing public hardships in this matter is more important than the balancing of putative private hardships.

(B) Effect on the Public Interest

It is good public policy to foster the development and distribution of new drugs and associated medical devices, through the fair and effective enforcement of our patent laws and the Hatch-Waxman addition to those laws. Failure to carry out that public policy can be seen as a public hardship. The position of Abbott in this litigation embodies this public policy issue. It is, however, also good public policy to see that the development and distribution of new drugs and medical devices is not impeded by misinterpretation or misapplication of our patent laws and the Hatch-Waxman addition. The position of Medtronic in this litigation raises the issue of carrying our this public policy.

In striking a balance between these public "hardships" it appears that there are two basic questions:"Is it in the public interest to allow the Medtronic Endeavor to enter the market?" "Is it in the public interest to retain the existing injunction?"

The Court believes that the answer to the first question is clearly "yes." Both common sense and case law support this answer. In Cordis Corp. v. Boston Sci. Corp., 99 Fed. Appx. 928, 935 (Fed. Cir. May 28, 2004)(unpublished) the Federal

Circuit stated that "strong public interest supports a broad choice of drug-eluting stents"; and in Cordis Corp v. Boston Scientific Corp, WL 22843072 (D. Del Nov. 21, 2003) the District Court noted the "obvious concern of depriving the public of the best and safest medical devices by limiting competition." The Medtronic Endeavor uses a polymer/drug coated stent, which in its bare metal stent version was previously used in the Medtronic Driver PTCA. As to that stent, the District Court, in the recent Delaware decision already noted, refers to the declarations of cardiologists, expressing their preference for using the Medtronic Driver with their patients, and of their concern for the success of their surgeries should the Medtronics products be removed from the market.

History also provides another insight into the significance of the '233 Yock patent RX to the overall PTCA Market. In 2006 Guidant Corporation was taken over by BSC. As of that time Guidant had acquired the '233 Yock patent from ACS. When the FTC reviewed the proposed merger, it was denied unless and until the '233 Yock patent was divested by Guidant, as the combination of BSC and Guidant would otherwise have too much market power. After Guidant sold the patent to its present owner, Abbott, the merger took place. See Phan Dec. ¶7, Ex. 6 (FTC Analysis of Agreement Containing Consent Order to Aid Public Comment, *In the Matter of Boston Scientific Corp. And Guidant Corp., File No. 061-0046* at 2).

Finally, Medtronic argues that the only other product on the market at the same advanced technological level as Endeavor

is the Abbott Xience. BSC's Promus product is the same product as Xience with another name, and J & J has no similar product on the market. Under these circumstances, If Endeavor is not available to the market there will be a negative market effect as the market will be reduced to only one available PTCA DES medical device at the latest technology level.

As to the second public interest question, the Court believes that the answer is that it is not in the public interest to maintain the present injunction. The '233 Yock patent has been extended on an interim but *de facto* basis by the PTO in order to give them time to consider the merits of a term extension. The decision of the PTO to grant an interim extension reads as though the only remaining task of the PTO is to decide the length of the FDA regulatory review, but that does not correctly describe the status of the extension review, as the PTO has the power to decide that an extension is not warranted and declare the extension to be void *ab initio*.

The rationale of Hatch-Waxman for an extension of a patent term is that it is unfair to the patent holder to be prevented from exploiting the invention in the market place during the time the FDA is reviewing the invention to decide if it can enter the market.

The PTO decision to grant an interim patent term extension for the '23 Yock patent was based upon the pre-market approval (PMA) by the FDA after the regulatory review of Abbott's Xience DES medical device. As already noted the Xience is a combination product with four primary components, one of which is an RX delivery system which is covered by the '233 Yock

patent. Again, as already discussed, the PTO has interpreted section 156 to mean that any "product" (the Xience), containing a component part (the RX delivery system), which is covered by a patent (the '233 Yock patent), is eligible for patent extension once it is granted a PMA. Even if one accepts this as an appropriate interpretation, which is dubious, it only interprets the "claims a product" term of Sec. 156(a), it does not resolve any other issued raised by Sec. 156 as a whole. Under the FDA rules, a regulatory review of a combination product is based on that product's "primary mode of action" which in turn is defined as "the single mode of action that provides the most important therapeutic action of the combination product." 21 C.F.R. §§ 3.4(a) and 3.2(m). A "mode of action" is "the means by which a product achieves the intended therapeutic effect or action." 21 C.F.R. § 3.2(k). As a matter of common sense, the RX is not a therapeutic component of the Xience, which means that the regulatory review of the Xience was not based on the RX, but rather on its therapeutic components, the stent and its coating. In essence, the RX plays the same role for the Xience PTCA as the spoon does when it delivers castor oil to the unhappy patient.

There is other support for the conclusion that the regulatory review of the Xinece did not focus on the RX component. An argument that the RX was in fact a product that was reviewed for safety and effectiveness at the time of the Xience review runs up against the requirement of sec. 156(a)(5)(A) that a PMA based on a regulatory review can trigger a patent term extension only when it is the first PMA

to permit commercial use of the product reviewed. The PMA for the Xience PTCA device is by no means the first PMA permitting commercial use for a PTCA with the RX system as a component part of the PTCA. At least four families of Abbott PTCAs with RX systems had already received PMAs before the FDA regulatory review of the Xience device. Nine different PTCA products of J&J and BSC with component RX systems had also been approved for commercial use through PMAs after regulatory review. The same is true for the Medtronic Endeavor and its predecessor, the Medtronic Driver. The RX system based upon the '233 Yock patent had been a component part of at least 100 PTCA medical devices issued PMAs by the FDA before the FDA reviewed it as a component part of the Abbott Xience device. See Motion at p.18.

In determining extension eligibility, the PTO interpretation of the term "claims a product," does not require that the FDA regulatory review of the "product," when it is limited to a review of only the component parts that are not covered by the patent at issue, will support term extension under Sec. 156. The record in this case does not show that the PTO has ever granted a Sec. 156 patent term extension for an invention that was not the basis of the regulatory review conducted by the FDA. From the perspective of this Court any such grant would misapply and distort the Hatch-Waxman Act.

To return to the underlying Hatch-Waxman rationale, did the regulatory review of the Xience prevent commercial exploitation by Abbott of the '233 Yock patent? Obviously not. The RX system based on the '233 Yock patent has been and enormous commercial success. Abbott and its corporate

predecessors have manufactured and sold thousands of PTCA medical devices, from simple balloon catheters, through BMS catheters to the current state-of-the-art DES catheters all enabled by the '233 Yock patent RX systems. These sales were made before, during, and after the time taken by the FDA to review the Xience PTCA device. At the same time, and even greater number of PTCA medical devices enabled by the RX system have been sold by BSC, J&J and its Cordis predecessor, producing revenue to Abbott as a result of the licenses for the patent. As far as the Court sees there has never been a day during the life of the '233 Yock patent where it has be unavailable for commercial exploitation. Once again, to grant a patent term extension under these circumstances because of the happenstance that yet another Yock RX enabled medical device was reviewed by the FDA would work a thorough distortion of Hatch-Waxman. Public policy in terms of making the most medical devices available to the public and also adhering to the principles underlying Hatch-Waxman, as well as the balance of relative hardships among the parties, comes down in favor of Medtronic.

V. Conclusion

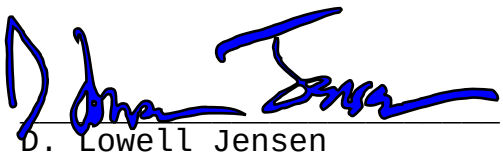
At this time, then, on this record, the Court is satisfied that the existing permanent injunction should not continue past the original expiration date of the '233 patent, October 29, 2008. Abbott will not suffer any irreparable injury, can receive an adequate remedy through damages, and does not prevail when competing hardships are assessed. Finally, an

equitable assessment of this case clearly supports an end to the injunction.

ACCORDINGLY, the permanent injunction is amended by deleting the words "or other legal expiration of the patent," and the injunction will stay in effect only until October 29, 2008.

IT IS SO ORDERED

Dated: October 21, 2008



D. Lowell Jensen
United States District Judge